Electronic database of arterial aneurysms

Base eletrônica de dados dos aneurismas arteriais

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Abstract

Background: The creation of an electronic database facilitates the storage of information, as well as streamlines the exchange of data, making easier the exchange of knowledge for future research. **Objective**: To construct an electronic database containing comprehensive and up-to-date clinical and surgical data on the most common arterial aneurysms, to help advance scientific research. **Methods**: The most important specialist textbooks and articles found in journals and on internet databases were reviewed in order to define the basic structure of the protocol. Data were computerized using the SINPE© system for integrated electronic protocols and tested in a pilot study. **Results**: The data entered onto the system was first used to create a Master protocol, organized into a structure of top-level directories covering a large proportion of the content on vascular diseases as follows: patient history; physical examination; supplementary tests and examinations; diagnosis; treatment; and clinical course. By selecting items from the Master protocol, Specific protocols were then created for the 22 arterial sites most often involved by aneurysms. The program provides a method for collection of data on patients including clinical characteristics (patient history and physical examination), supplementary tests and examinations, treatments received and follow-up care after treatment. Any information of interest on these patients that is contained in the protocol can then be used to query the database and select data for studies. **Conclusions**: It proved possible to construct a database of clinical and surgical data on the arterial aneurysms of greatest interest and, by adapting the data to specific software, the database was integrated into the SINPE© system, thereby providing a standardized method for collection of data on these patients and tools for retrieving this information in an organized manner for use in scientific studies.

Keywords: aneurysm; database; data collection.

Resumo

Contexto: A criação de um banco de dados eletrônico facilita o armazenamento de informações e agiliza o cruzamento de dados, tornando mais fácil a troca de conhecimentos para futuras pesquisas. **Objetivo**: Criar uma base de dados clínicos e cirúrgicos informatizada, de uma forma abrangente e atualizada, dos aneurismas arteriais mais frequentes, para auxiliar na realização de estudos científicos. **Métodos**: Foram selecionados os principais livros-texto da especialidade e artigos retirados de revistas e de bases de dados ligados à rede internacional de computadores (Internet), para que servissem de base estrutural do protocolo. A informatização dos dados foi realizada através da interface do programa SINPE© (Sistema Integrado de Protocolos Eletrônicos) e testada por um projeto piloto. **Resultados**: Com a informatização dos dados, criou-se o protocolo mestre, o qual abrange grande parte do conteúdo das doenças vasculares, sendo organizado em pastas principais; em seguida, foram criados 22 protocolos específicos dos sítios arteriais aneurismáticos mais predominantes, originados das informações contidas no protocolo mestre. O programa permite a coleta de dados de pacientes com suas características clínicas (anamnese e exame físico), exames complementares, tratamento realizado e o seguimento pós-tratamento. Qualquer informação de interesse destes pacientes que conste no protocolo pode ser cruzada, de acordo com o estudo que se queira realizar. **Conclusões**: Foi possível a criação da base de dados clínicos e cirúrgicos, relacionada aos aneurismas arteriais de maior interesse, adaptando estes dados a software específico; este dispositivo foi incorporado no SINPE©, possibilitando um meio para coleta de dados de pacientes, assim como o resgate destas informações de forma organizada para uso em estudos científicos.

Palavras-chave: aneurisma; base de dados; coleta de dados.

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INTRODUCTION

Healthcare professionals and their specialist medical societies and also hospital managers are constantly seeking high quality medical literature that can be used to provide parameters for medical conduct and to help guide hospitals when buying and making available new technologies to benefit patients.[1]

In the fifth century BC, Hippocrates of Cos was one of the pioneers of attempts to institutionalize the science of medicine, demonstrating the importance of keeping records on patients with the objective of reflecting the course of diseases in an exact manner and attempting to indicate their possible causes, and as such he is considered one of the first people to begin to create medical scientific literature and to keep clinical records.[2]

As information technology has evolved over recent years and access to computers and, in particular, the Internet, has become widespread, it has become possible to immediately access the most up-to-date results of clinical research. This, in turn, has facilitated application of the principles of evidence-based medicine, which is the link between good scientific research and clinical practice.[3]

Similarly, application of protocols to the construction of large-scale clinical databases can improve the quality of medical research by providing a trustworthy source of scientific research.[4,5] One example of this is the way that the University of Alabama has become an international leader with regard to patients with Acquired Immunodeficiency Syndrome (AIDS) through publication of scientific research based on clinical data stored in a computerized system.[6]

In Great Britain, the Vascular Society of Great Britain and Ireland set up a national database in 1997 that can be accessed by the society's members, after registration. The objective is to accumulate information on abdominal aortic aneurysms, revascularization of lower limbs and amputations, with the aim of improving the quality of the services provided to patients and, in the future, to aid with treatment decisions.[7]

The development of a database in electronic format containing information on patients admitted with arterial aneurysms should prove a useful resource for future clinical research into the subject because aneurysmal arterial diseases have a highly varied clinical presentation, since diagnosis can vary from emergency scenarios, in which there is risk of loss of limbs or even of death, to cases in which the disease is discovered during routine examinations or during work up for a different disease.[8]

The objectives of this study are as follows:

1- To create a wide-ranging and up-to-date database (electronic protocol) on the most common arterial aneurysms involving 22 different arteries;

2- To computerize this database in a standardized manner, adapting it to a specific software program called the Multidisciplinary Vascular Diseases Protocol, designed for data collection, which is itself part of an Integrated Electronic Protocols System (SINPE©).

MATERIAL AND METHODS

Development of the electronic protocol was conducted in three stages. The first step was to conduct a review of the literature in order to define the data structure. The second step was to input this information into the system, initially creating a master protocol, which was then used to develop the specific protocol. The final step was to integrate the electronic database of clinical and surgical data on 22 types of arterial aneurysm into the SINPE© system.

Literature review and data structure

Material on the chosen subject (arterial aneurysms) was selected for data collection. The most important text books were consulted, as follows: Cirurgia Vascular (Vascular Surgery),[9] Doenças Vasculares Periféricas (Peripheral Vascular Diseases),[10] Cirurgia Endovascular (Endovascular Surgery),[11] Vascular Surgery,[12] Mastery of Vascular and Endovascular Surgery,[13] Haimovici's Cirurgia Vascular (Vascular Surgery),[14] Decision Making in Vascular Surgery[15] and Aneurismas (Aneurysms).[16] These books cover the most recent updates and reviews and provided the initial structure for the protocol.

A total of 22 different arterial aneurysm sites were chosen for specific protocols on the basis of their prevalence and of academic research interest in them, excluding the intracranial arteries and the ascending aorta, since these are the preserve of the specialties of neurosurgery and heart surgery respectively.

A specific and detailed review of the literature was then conducted on electronic medical libraries via the Internet and in specialized vascular surgery journals, in addition to the textbooks mentioned above.

The following addresses were used for the Internet search: http://regional.bvsalud.org/php/index.php, http://www.medscape.com and www.pubmed.gov, because they offer the most complete searches of medical research archives. Articles used in this study that were published before 1999 were identified in the references of textbooks or of articles found in earlier search stages.

The 22 arterial sites most often involved in aneurysmal disease according to the 2008 version of the International Statistical Classification of Diseases and Related Health Problems – ICD-10[17] were also listed and saved in Microsoft Word XP® files, as follows:

ABDOMINAL AORTIC ANEURYSM (I71.4, I71.3)

THORACIC AORTIC ANEURYSM (I71.2, I71.1)

THORACOABDOMINAL AORTIC ANEURYSM (I71.6, I71.5)

POPLITEAL ARTERY ANEURYSM (I72.4)

ANEURYSM OF COMMON FEMORAL, FEMORAL PROFUNDIS AND SUPERFICIAL FEMORAL ARTERIES (I72.4)

ANEURYSM OF COMMON, INTERNAL AND EXTERNAL ILIAC ARTERIES (I72.4)

ANEURYSM OF CAROTID ARTERIES (I72.0)

ANEURYSM OF VERTEBRAL ARTERIES (I72.8)

ANEURYSM OF BRACHIOCEPHALIC TRUNK (I72.8)

ANEURYSM OF SUBCLAVIAN ARTERIES (I72.1)

ANEURYSM OF AXILLARY ARTERIES (I72.1)

ANEURYSM OF SPLENIC ARTERY (I72.8)

ANEURYSM OF RENAL ARTERIES (I72.2)

ANEURYSM OF COMMON HEPATIC ARTERY (I72.8)

ANEURYSM OF SUPERIOR MESENTERIC ARTERY (I72.8)

ANEURYSM OF INFERIOR MESENTERIC ARTERY (I72.8)

ANEURYSM OF GASTRODUODENAL ARTERY (I72.8)

ANEURYSM OF CELIAC TRUNK (I72.8)

Entry of data onto the system and creation of the Master and Specific protocols

The software responsible for management of the data has been in a process of constant improvement since the start of the 1990s. This software is the intellectual property of Prof. Dr. Osvaldo Malafaia and has been registered with the Brazilian patents authority (INPI - Instituto Nacional de Propriedade Industrial) under number RS-6056-1. This software is the backbone of a research project called the Integrated Electronic Protocols System (SINPE©).[18]

The SINPE© database is managed by ACCESS©, which facilitates storage and distribution of the program on CD-ROM. The programming language employed is C# (C-Sharp), and the Microsoft®. NET Framework is used to organize, populate and manipulate stored data. The program is simple to install and the minimum system requirements are 32 megabytes of RAM memory and a 500 megabyte hard drive.

The program's developers granted the permissions necessary to create and modify databases to the administrator of the arterial aneurysm protocol. After installation of the program, a dialog box opens, as shown in Figure 1, for the user to input their details. There are four levels of access permission: administrator, researcher, data collector and read-only user. Common passwords are provided to researchers, data collectors and read-only users, i.e. those who need to view content, collect data or store information. However, it is only with administrative permissions and passwords that it is possible to develop and change the content of protocols. For the purposes of this study, administrator privileges were granted.

The method chosen to organize the data acquired for the arterial aneurysm protocols on the computer was to allocate two different storage locations. All 5,092 data items related to the majority of vascular

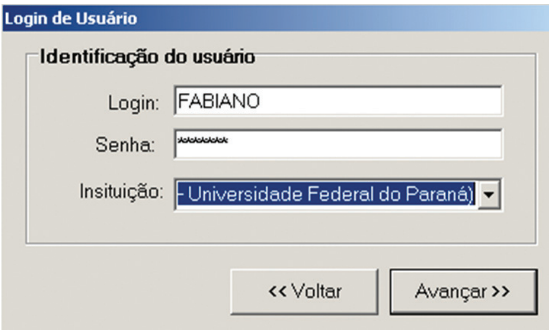

Figure 1. Enter login, password and institution.

diseases were stored in the first of these, termed the Master protocol, duly organized into a series of top-level directories, classified didactically into the following categories: patient history, physical examination, supplementary tests and examinations, diagnosis, treatment and clinical course.

The second storage location, containing the Specific protocols, is subdivided into the 22 arterial aneurysm sites listed above, each populated with the relevant data from the Master protocol, and classified into the same directory structure as in the Master protocol. Each item is added using the buttons on the Master protocol taskbar (Figure 2). The program uses a tree directory structure and will automatically display a plus sign (+) next to subject headings that have subitems (children). Once the specific protocols had been created (for each of the 22 arterial sites), the content for each disease and their characteristics were added. Adding items to protocols is simple. The protocol editing screen has a drop-down list of the 22 specific protocols that have been created (Figure 3) and then the two arrows in the center of the form are used to add or remove the items stored in the Master protocol to or from the protocol for a specific disease. In this manner each specific protocol is constructed from the information contained in the Master protocol

Integration of the electronic database of clinical and surgical data on arterial aneurysms into the SINPE© system

The Master and Specific protocols had been populated with data in a manner that allowed for integration into the SINPE© system. The underlying motive for creating this system was to enable other investigators at different centers to conduct research

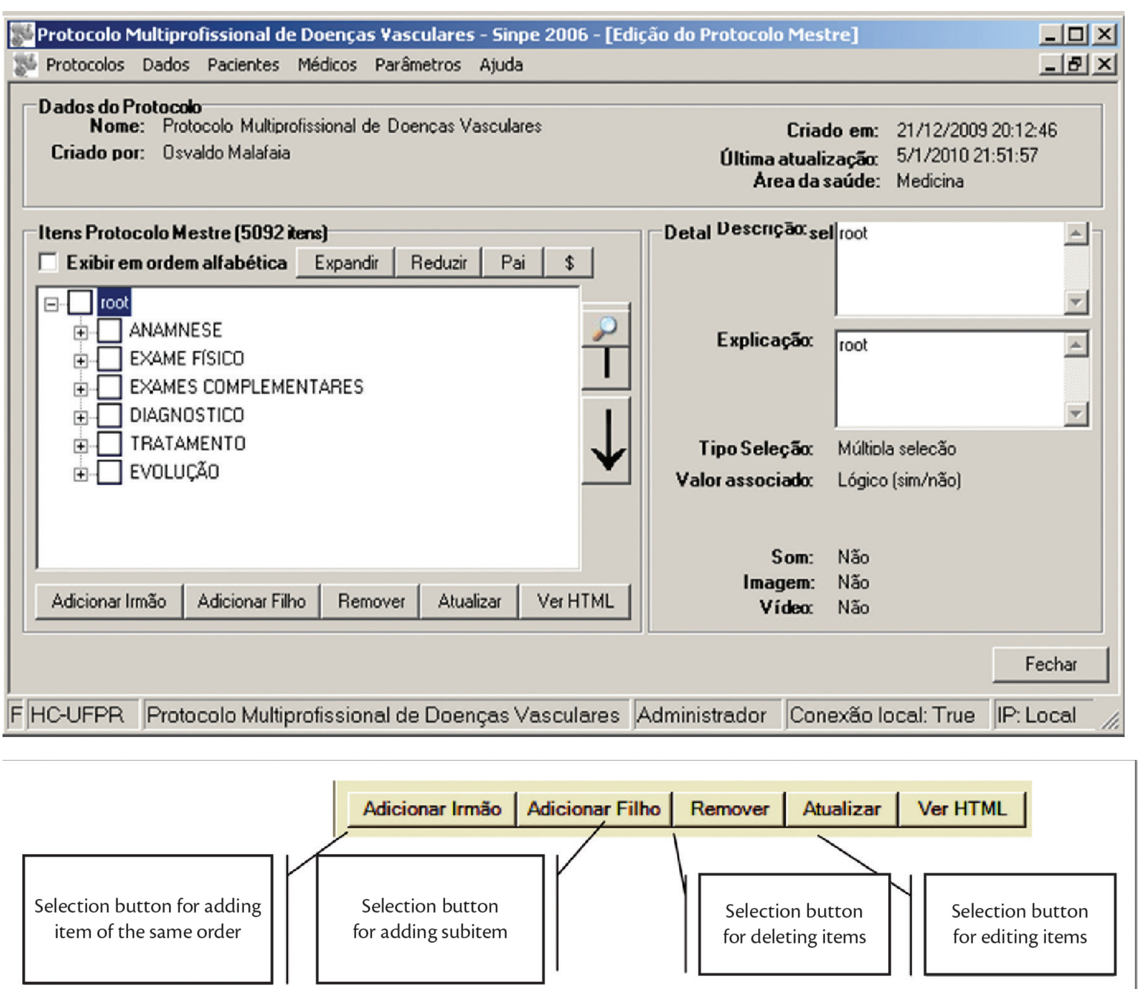

Figure 2. Master protocol taskbar.

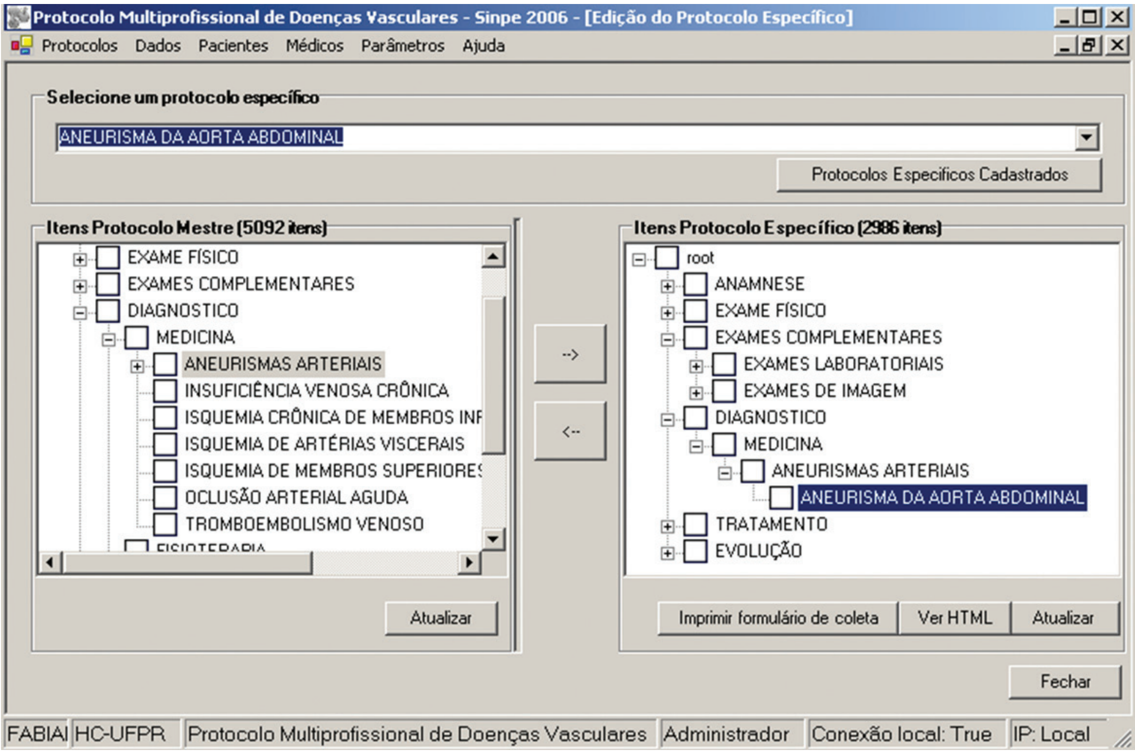

Figure 3. Specific protocol for abdominal aortic aneurysms.

and data collection and so the program can be controlled remotely. Access over the Internet is via www.sinpe.com.br. The program is hosted within the Internet Explorer® platform and can only be accessed by users who have been issued a password. Other interfaces have also been developed for use on mobile computing devices, such as tablets, PDAs and smartphones. The wide variety of platforms that can access SINPE© offers great ease and flexibility for data collection.

A pilot study was conducted at Hospital de Clinicas da UFPR to test the protocol's feasibility by conducting retrospective data collection from medical records for the last 17 patients seen at the vascular surgery service who had undergone elective surgery to repair infrarenal abdominal aortic aneurysms during the previous 5 years. The electronic protocol was also tested for the last seven patients with infrarenal abdominal aortic aneurysm, seen at Hospital São Lucas, with the objective of including data on patients who had undergone elective endovascular treatment. After data collection, another module called the SINPE Analyzer is used to interpret information, providing an interface that enables a rapid overview of the data items in the SINPE electronic protocols and offering functions for plotting graphs, conducting statistical analysis, printing and saving results and exporting data.

The pilot project was approved by the Ethics Committee, under number 2008023344.

RESULTS

With the Master protocol open, all of the top level directories can be seen, with the total number of items shown above. The plus sign (+) next to the top-level directories show that they contain subitems that can be opened. For example, the subitems that comprise patient history are as follows: asymptomatic; symptomatic; personal history of morbidity/risk factors; family history of morbidity, and living conditions and lifestyle habits. These, in turn, also have branches, so, for example, choosing the 'SYMPTOMATIC' subitem will reveal the 44 symptoms identified as related to vascular diseases and which may themselves also contain subitems. The same format is used for all of the subitems in the Master protocol, although the number of branches varies (Figure 4).

The six items shown in the main window are termed 'top level directories' and each contains a number of subitems, categorized in a didactic manner

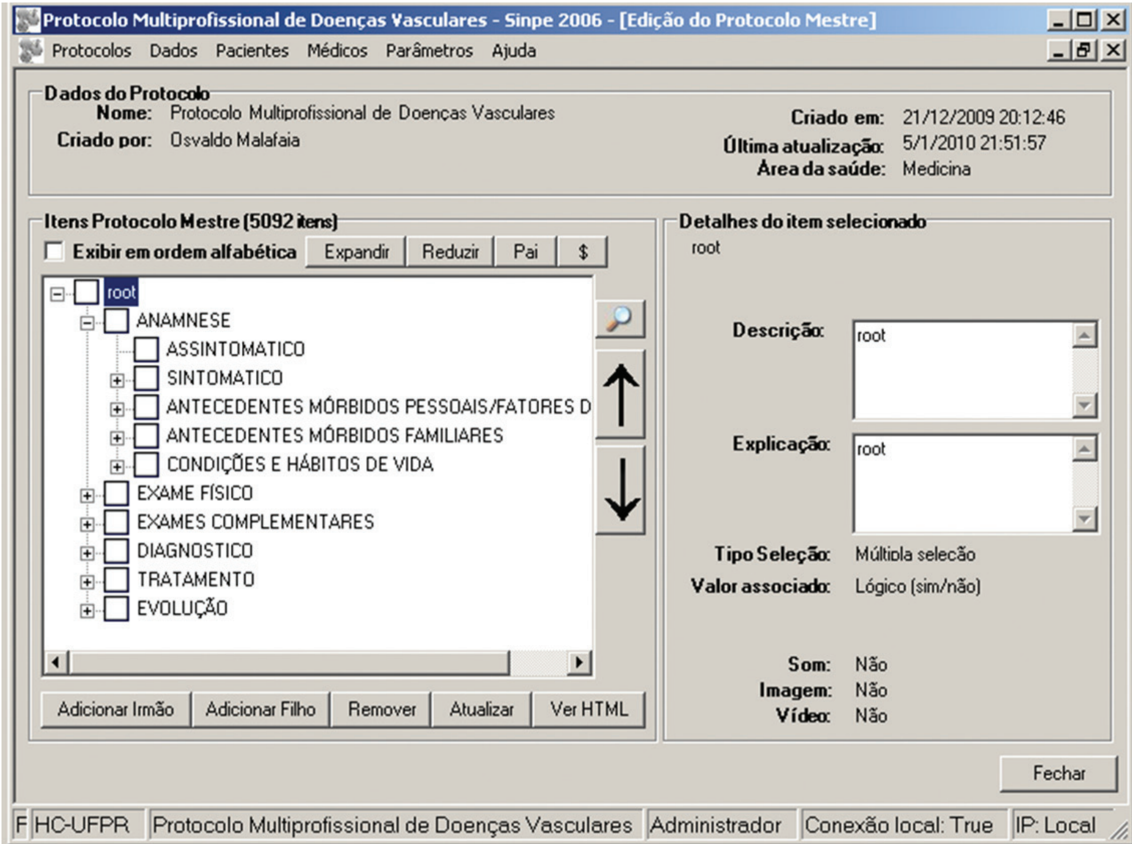

Figure 4. Master protocol with items and subitems.

in order to facilitate the process of adding items to specific protocols. The program also has a "Médicos" menu which opens a dialogue box for registering the physicians who will be responsible for entering data (Figure 5) and another menu that opens a patient registration form for inputting identification details (Figure 6).

Each patient is assigned a unique code by the program to avoid the possibility of entering their data more than once. The system requires three obligatory fields indicated in blue to create a new patient record, for name, sex and skin color (Figure 6), and will not register a new patient if these details are identical to an existing record. At the start of a data collection process, the program requires the user to choose a specific protocol (for the disease in question), the patients involved and the treating physician. After entry of identification details, a new screen opens with check marks against the items related to each patient. Once data entry is complete, the system can be used to conduct data queries for statistical purposes, returning lists of all the data collections found for a given set of search criteria. The user selects the data items and type of search required

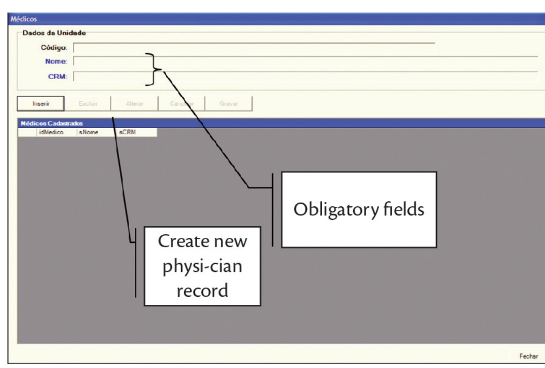

Figure 5. Physician registration.

and then clicks on the "run search" button to view the results (Figure 7).

Using searches provided within the program, data that will be used for research can be retrieved and grouped and divided by specific criteria and queried as soon as patient data has been entered via the protocols. The database can be queried automatically inside the program itself or data items can be grouped manually, using an interface specially developed for viewing the results and offering automatic generation of graphs and tables (the SINPE Analyzer).

APPLICATION OF THE ELECTRONIC PROTOCOL

Data was input on a total of 24 patients with diagnoses of infrarenal abdominal aortic aneurysm who had received surgical treatment. Three of these patients were female (12.5%) and the remaining 21 were male (87.5%). Age varied from 68 to 82 years with a predominance of 29.17% aged between 75 and 82 years (Figure 8) and a mean of 75 years. The patients' skin colors were yellow (n=1, 4.17%) and white (n=23, 95.83%) (Figure 9). There was a majority of male patients 87.5% and a minority (12.5%) of females (Figure 10).

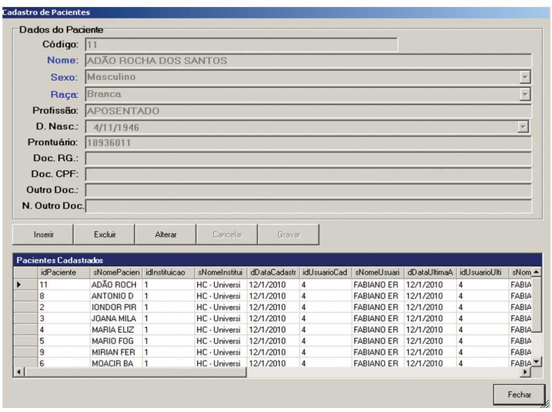

Figure 6. Patient registration.

Risk factors included smoking, found in 15 patients, followed by personal history of morbidity, systemic arterial hypertension, heart diseases and chronic obstructive pulmonary disease as the most common diseases in this sample (Figure 11).

With relation (or relationship or ratio) to diagnosis of these patients, more than half were asymptomatic (58.33%) (Figure 12). Of the ten symptomatic patients, nine had exhibited abdominal pains, which, in the majority of cases, were chronic (Figure 13). Abdominal swelling was detected in all cases during physical examination on admission and in 70.83% of cases tomographic imaging exams were used to confirm diagnosis and plan treatment (Figure 14).

The majority of patients (91.3%) had abdominal aortic aneurysms with a fusiform morphological classification and just two patients had saccular aneurysms (Figure 15).

The most common surgical treatment employed was an aortoiliac shunt, in 40% of the patients (Figure 16), whereas bifurcated endoprostheses were used in all patients who underwent endovascular repair.

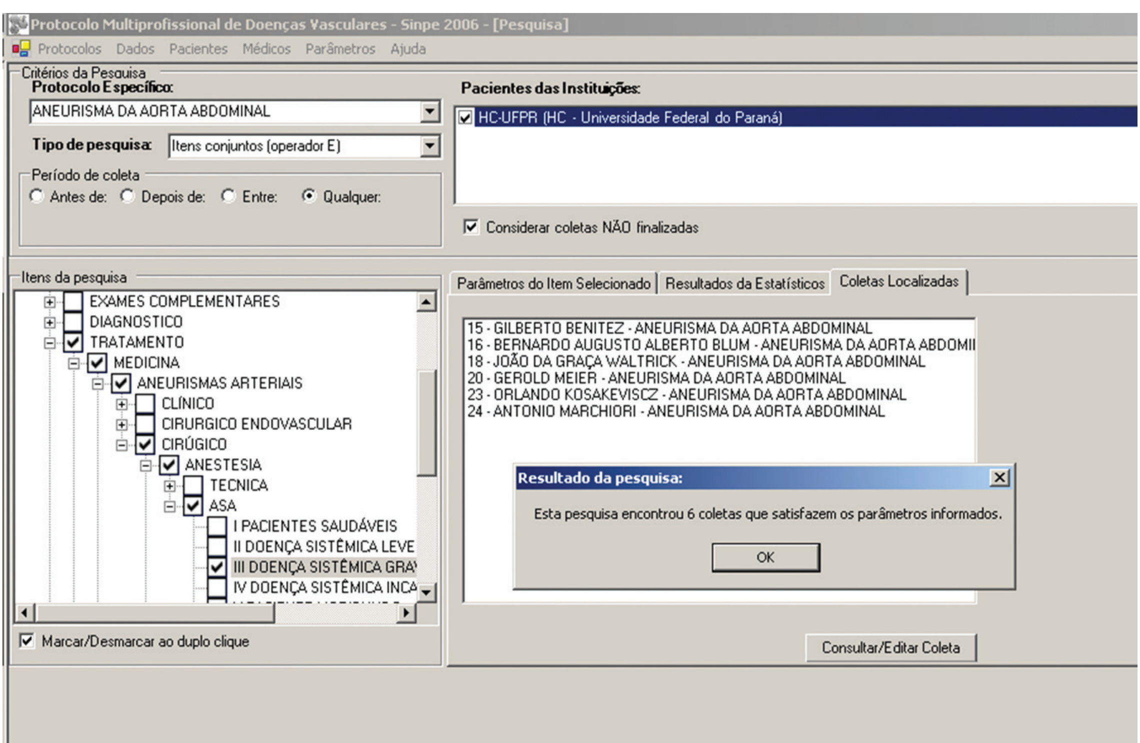

Figure 7. Example study.

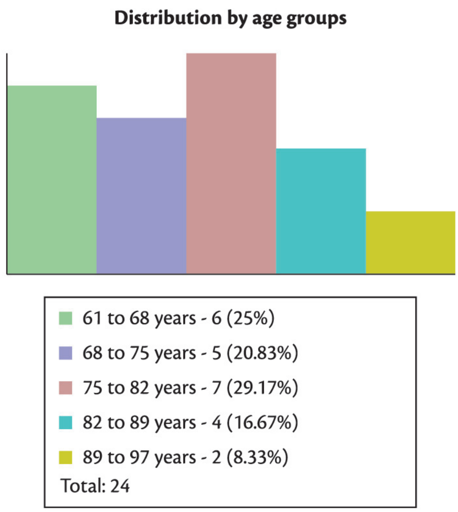

Figure 8. Distribution by age group.

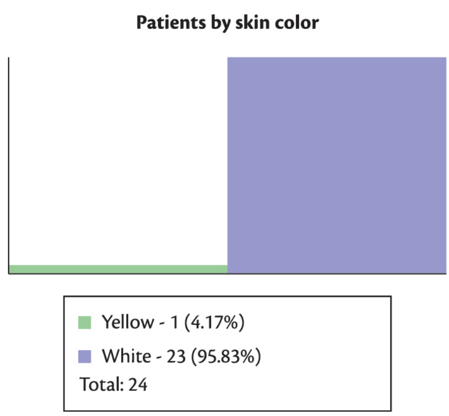

Figure 9. Distribution by skin color.

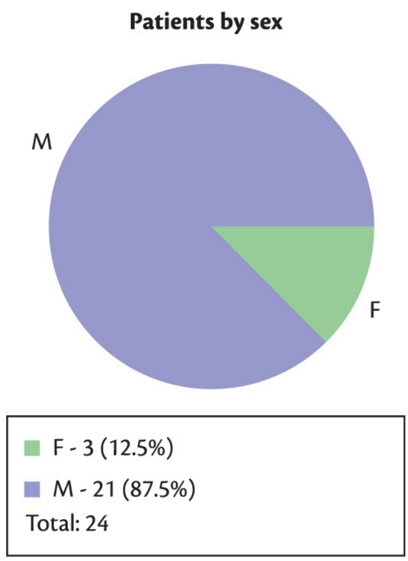

Figure 10. Distribution by sex.

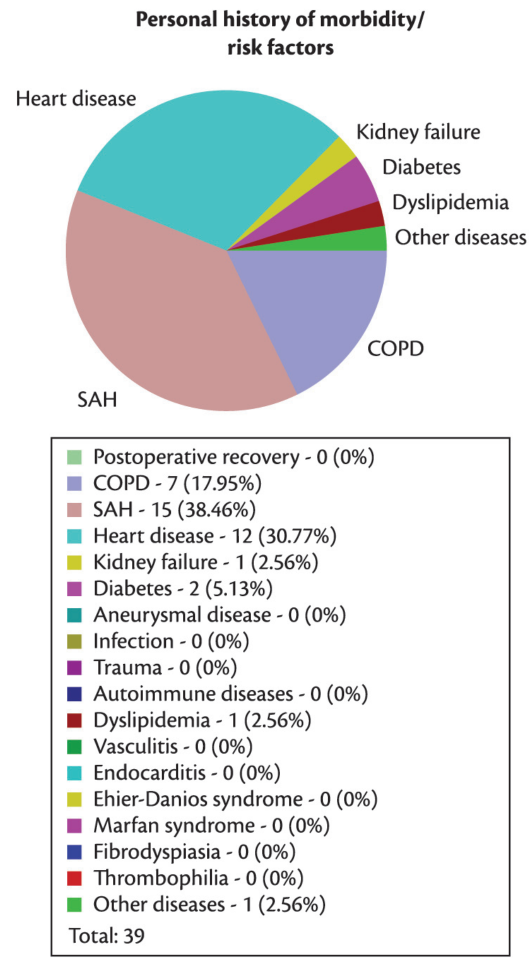

Figure 11. Risk factors.

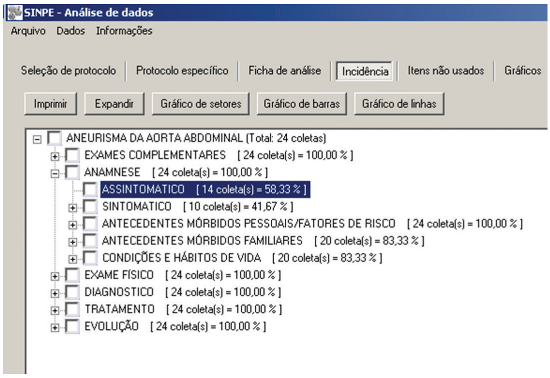

Figure 12. Asymptomatic patients.

DISCUSSION

Digitalization of clinical data

The information about patients that is contained in their files is very important because it can be used to guide the health system of a country, which is established thanks to what has been documented

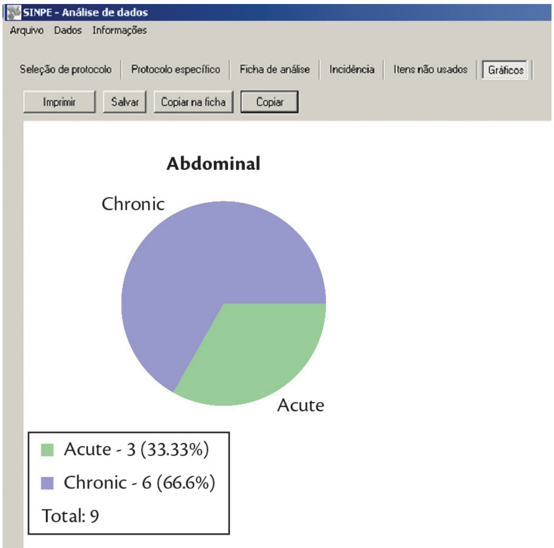

Figure 13. Symptomatic patients with abdominal pains.

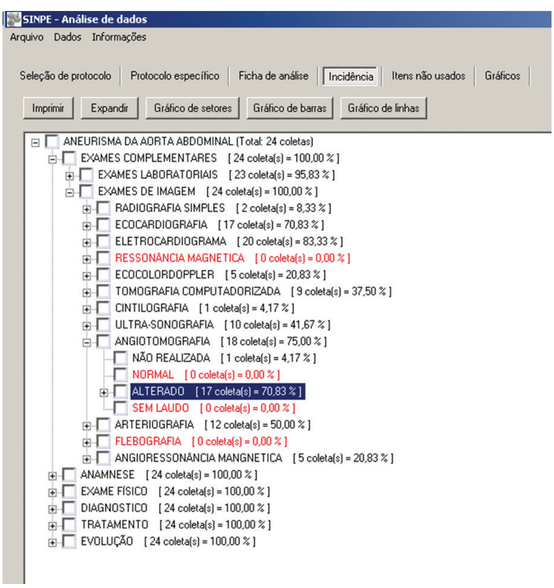

Figure 14. Supplementary tests and examinations.

in the medical record. Taken together, these data describe the state of a population's health and enable construction of policies and models of healthcare provision and management. Longitudinal records that cover individual patients' entire lives can be used to construct databases containing aggregated, clinical and administrative information, and which in turn have been recognized as being highly effective and beneficial for improving efficacy, efficiency, safety and quality of practice in healthcare.[19]

The process of harvesting clinical data can be time consuming because of poor quality of many patient

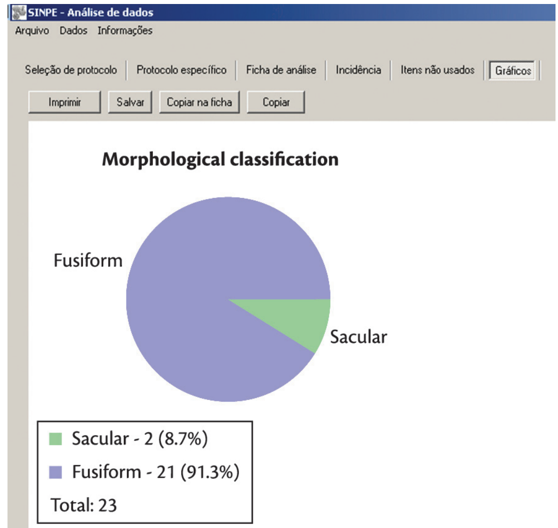

Figure 15. Morphology of abdominal aortic aneurysms.

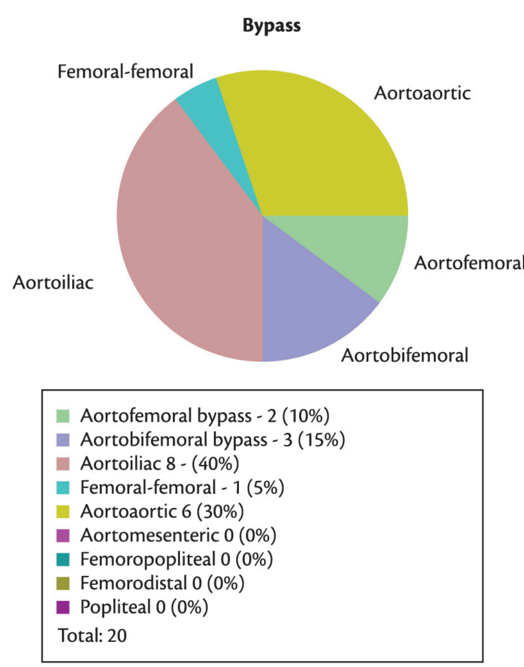

Figure 16. Surgical treatments.

medical records, among other reasons. Patients' clinical histories may be incomplete and are often in the handwriting of many different professionals (which is a common finding in university medical settings), making it much more difficult to correctly evaluate the data items contained in the patient records, compromising the credibility of the database and throwing up barriers to high quality research.[20,21] Also of relevance are the constant developments in techniques for examinations, tests, diagnosis and treatment, which generate increasing volumes of clinical information on each patient. The expansion in clinical specialties has made it possible to widen patient care and involve a larger range of different professionals, creating a need to find a more rapid and simpler method for these professionals to access patients' medical records.

During the 1990s, the IT department at the Hospital das Clínicas da Universidade de São Paulo's Heart Institute (InCor) pioneered implementation of a digital hospital information system to store the institution's administrative and clinical data. They developed an electronic medical records system using the Internet that provides an integrated system for accessing all patient data in a simple and standardized manner.[22]

For a long time computers were only seen in the administrative and managerial departments of hospitals, but nowadays the use of IT in medicine is very well established. In the United States and Europe, computers are used at the bedside and patient visits are conducted with a laptop that can be used to access all data on patients' vital signs and daily clinical progress. Computers are also becoming more widely used in Brazilian hospitals, particularly by the nursing teams and for access to electronic patient records.

Leape, Bates and Christalkis observed that the switch from manual to electronic prescriptions for administration of medications to patients was accompanied by a significant reduction in medical errors, bearing in mind that 50,000 deaths a year are attributed to potentially avoidable medical errors in the United States alone.[23-25]

Implementation of an electronic data collection system for creation of patient medical records facilitates searching and retrieval at a later date, makes it possible to constantly update information in an organized manner and provides a foundation for future research. However, the greatest barriers to implementation are the cost of purchasing computers and software and a lack of human resources, i.e. of people trained to provide adequate maintenance after implementation. Considering that both medicine and IT are in a permanent state of development, a good database must have a structure that can be modified in order to adapt to new developments.

Large medical centers in the United States and Europe have turned to IT (in the form of electronic protocols) to solve the problems caused by paper-based medical records, i.e. they have adopted routine use of computers to create and update patient records while simultaneously collecting relevant clinical data in a standardized manner, thereby avoiding the limitations and subjective character of traditional medical records.[26-28]

However, electronic protocols alone are in no way a substitute for patients' medical records. The major difference between the two is that the protocol contains sources of information about a given group of diseases, in contrast with the patient record, which is specific to an individual patient and is not written according to rigid rules. The patient record must be kept up-to-date by the physician for the purposes both of monitoring the patient and of creating a legal record of the patient's care. In common with research protocols, electronic versions of patient medical records are becoming ever more common. The objective of this gradual process of change is to rationalize the use of the time available for medical consultations and improve ease of access to patients' medical histories.[29]

Along the same lines, employing protocols when compiling large databases of clinical data can improve the quality of medical research by providing a trustworthy source of scientific research.[30-32] Data bases can be used by individual universities alone or they can be pooled to construct multicenter databases, as has been done in France, where 38 different intensive care units employ a standardized data format and store their data in a single database,[33] or in Italy, where there are multicenter studies related to liver diseases using shared data.[34]

One example of such a database in Brazil is maintained by the Brazilian Association of Intensive Care Medicine (AMIB) and can be accessed on-line (www.amib.com.br), providing up-to-date information on the most important intensive care units (ICUs) in Brazil, allowing exchange of information and analysis between the member ICUs.

It is clear that digital collection of clinical data encourages and facilitates multicenter studies, increasing the quantity of data available and improves the quality of scientific studies, whilst also offering the benefits of reductions in time spent on research, larger study populations and faster and more precise results.[35]

With regard to construction of electronic protocols using the SINPE© software

The basic principle of SINPE© is related to creating an electronic protocol for collection of clinical data that is capable of generating a high-quality database prospectively and is characterized by a simple method for populating and managing the data[18], thereby helping to reduce the time taken to produce scientific articles, Masters Dissertations and Doctoral Theses.

The electronic protocol was programmed in the Microsoft® C# language, which facilitates adaptation of the system to use the Internet and for running on platforms such as handheld computers (PDAs and tablets), offering portability and widening the scope of its applications. The file created by Access® was employed to enable the electronic protocols program to be employed independently on other computers, which is itself the main reason for employing the program's local connection, offering a minimum risk of incompatibility at runtime.

To date, more than 100 diseases have been registered on the SINPE© system and approximately 120,000 data items have been entered, covering a wide range of the medical specialties and also other healthcare disciplines, such as Physiotherapy, Nursing and Nutrition.

Even taking into consideration the years of research and the initial investments, the cost of implementing SINPE is relatively low in view of its importance and scope. Research will always be the pillar that supports the development and advancement of Medicine.

With regard to the task of reviewing the literature and selecting bibliographic material

The idea of including all vascular diseases on this electronic protocol came up against the barrier of the large number of such diseases, many of which are not observed in daily practice because of their low incidence and diverse range of clinical presentations. As such, the protocol would have contained a very long list of diseases and the great majority of users would have found difficulties with handling it.

The decision was therefore made to choose the diseases that are most frequently encountered in clinical practice, according to the literature consulted, and supplement them with a number of diseases that are not so common, but are of epidemiological importance and academic interest because they have been the subjects of few prospective studies. One example of this is aneurysms of the renal arteries of hypertense patients, for which best practice has not yet been defined, since the impact this type of aneurysm has on renal function is not yet known. Adoption of the electronic information system provides a method for collecting information on the subject and provide a basis for future studies.

Medical developments, inventions and discoveries have not been forgotten in the design of the electronic protocol, since it is possible to add new items without affecting the database that is already in use. However, due to issues related to the security of the data that have been input and their confidentiality, such alterations can only be made by users with administrator privileges and not by data collectors, read-only users or researchers.

CONCLUSIONS

The electronic protocol for vascular diseases in arterial aneurysms was created after initially constructing a database of clinical data, which was done by entering all data onto a Master protocol that covers the majority of vascular diseases. This Master protocol was then used to create a series of Specific protocols on each of the most common types of arterial aneurysm, thereby providing a standardized method for collection of data on these patients and tools for retrieving this information in an organized manner for use in scientific studies. The result is a uniform and reliable method for acquisition and storage of clinical and surgical data that can then be made available for use in future research.

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